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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,125	08/30/2005	Dorian Bevec	69137-00003USPX	5536

61060 7590 07/12/2007

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,125	BEVEC, DORIAN	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-10, in the reply filed on 4/12/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-19 are pending; claims 11-19 are withdrawn for pertaining to a non-elected invention.

Sequence Compliance

2. This application is objected to because the peptide sequence in claim 4 is not associated with a sequence identifier (a SEQ ID NO) and is not included in the Sequence Listing. All sequences longer than ten nucleotides or four amino acids referenced in the specification must include a SEQ ID NO and must be included in the Sequence Listing. See MPEP § 2421-2422 and Notice to Comply.

Specification

3. The abstract of the disclosure is objected to. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

4. The Information Disclosure Statement filed 6/8/2006 has been considered. Non-patent literature references must include a title. Citations C3, C4 and C14 should be updated to include titles.

Claim Objections

5. Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112/101

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-10 provide for the use of peptides, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. For the purposes of examination, claims 1-10 are being interpreted as composition claims.

11. Claims 4-7 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claim 4 recites the limitations "A,B" and "n,m" in the formula of that claim but the formula does not contain the variables "A,B" and "n,m". There is insufficient antecedent basis for this limitation in the claim. Claim 5 recites the limitations "X,Y" and "o,p" in the formula of that claim but the formula does not contain the variables "X,Y" and "o,p". There is insufficient antecedent basis for this limitation in the claim. Claim 6 recites the limitations "X',X''" and "r,q" in the formula of that claim but the formula does not contain the variables "X',X''" and "r,q". There is insufficient antecedent basis for this limitation in the claim. Claim 7 recites the limitation "X^1-X^{22}" in the formula of that claim but the formula does not contain the variable "X^1-X^{22}". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-10 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Block (WO 02/43746, cited in the office action mailed 10/11/2006). Block teaches VIP, a 28 amino acid peptide consisting of HSDAVFTDNYTRLRKQMAVKKYLNSILN (SEQ ID NO: 1,

page 3). Regarding claim 1, VIP comprises claimed SEQ ID NO: 4. Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOs: 14 and 13. Regarding claim 4, Block teaches a polypeptide having the sequence A_n-RKQMAVKKYL-B_m where A and B are independent and are any naturally occurring amino acid, and n and m are independent and have integer values ranging from 0-25 (page 7, lines 20-25). The polypeptide HSDAVFTDNYTRLRKQMAVKKYLNSILN (SEQ ID NO: 1, page 3) satisfies the limitation of claims 5 and 6. Regarding claim 5, X=HSDAV, o=5, Y=NYTRL and p=5. Regarding claim 6, q=0, X''=AV and r=2. Regarding claim 7, Block teaches polypeptides identical to species i-vii and x (page 7, line 25 through page 8, line 10). Regarding claim 8, Block teaches a stabilized form of the polypeptides (page 10, lines 20-29). Regarding claim 9, Block teaches that the polypeptides have the biological function of VIP or PACAP or any biologically active derivative, truncated for, analogue or fusion protein thereof (page 9, line 20 through page 10, line 19). Regarding claim 10, Block teaches formulating the peptides as an aerosol for inhalation (page 16, line 9, page 17, line 10).

14. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

15. Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi *et al.* (EP 0 613 904, citation B8 on the Information Disclosure Statement filed

6/82006). Takahashi *et al.* teach pharmaceutical compositions comprising VIP and its analogues. Regarding claim 1, the polypeptide includes claimed SEQ ID NO: 4 (Table 1, line 1). Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOs: 14 and 13 (Table 1, line 1). Regarding claim 4, the polypeptide has the sequence A_n-RKQMAVKKYL-B_m where A is HSDAVFWDNYT, B is NSILN, n is 10 and m is 5 (Table 1, line 1). Regarding claim 5, X=HSDAV, o=5, Y=NYTRL and p=5. Regarding claim 6, q=0, X''=AV and r=2. Regarding claim 7, the polypeptide is identical to SEQ ID NO: 1(Table 1, line 1). Regarding claim 9, the polypeptides have the biological function of VIP (page 3, lines 25 and 26). Regarding claim 10, the polypeptide may be formulated for inhalation (page 4, line 33).

16. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda *et al.* (EP 0 663 406, citation B9 on the Information Disclosure Statement filed 6/82006). Noda *et al.* teach pharmaceutical compositions comprising VIP and its analogues. Regarding claim 1, the polypeptide includes claimed SEQ ID NO: 4 (abstract, SEQ ID NO: 2). Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOs: 14 and 13 (Table 1, line 1). Regarding claim 4, the polypeptide has the sequence A_n-RKQMAVKKYL-B_m where A is HSDAVFWDNYT, B is [N,K,Q]KAL[KR]homoserine, n is 10 and m is 5 (Table 1, line 1). Regarding claim 5, X=HSDAV, o=5, Y=NYTRL and p=5. Regarding claim 6, q=0, X''=AV and r=2. Regarding claim 7, Nado *et al.* teach a polypeptide that is identical to SEQ ID NO: 1(page 3, SEQ ID NO: 1). Regarding claim 8, the polypeptides are in a stabilized form (abstract). Regarding claim 9, the polypeptides have the biological function of VIP (page 4, line 21). Regarding claim 10, the polypeptide may be formulated for inhalation (page 5, line 8).

17. Neither Block, Takahashi *et al.* or Noda *et al.* teach that the polypeptides can be used to treat patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis. Because the chemical structure of the species taught by Block, Takahashi *et al.* or Noda *et al.* are identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112).

18. If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP § 2112.01. Examiner cannot however determine whether or not the polypeptides taught by Block, Takahashi *et al.* or Noda *et al.* inherently possess properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

20. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

21. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/501,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to pharmaceutical compositions comprising identical polypeptides. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, 15 and 18 of copending Application No. 10/564,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to pharmaceutical compositions comprising identical polypeptides. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)

272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.
Patent Examiner
Art Unit 1654

cmb

Cecilia Tsang
Supervisory Patent Examiner
Technology Center 1600

Notice to Comply	Application No. 10/517,125	Applicant(s) BEVEC, DORIAN	
	Examiner Christina Marchetti Bradley	Art Unit 1654	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The amino acid sequence in claim 4 requires a SEQ ID NO.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-0731 or (571) 272-0951
For CRF Submission Help, call (571) 272-2510
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Technical Assistance.1-866-217-9197 or 703-305-3028 or 571-272-6845
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